EFFOP
Marine Nutrients Europe

Public consultation on the Food and Feed Safety – Simplification Omnibus

EFFOP – Marine Nutrients Europe represents European producers of marine ingredients, an industry that is both economically and environmentally of strategic importance. Our members transform responsibly managed marine resources into high-quality proteins and nutrients, including essential omega-3 fatty acids, thereby contributing to food security and healthy diets.

Firstly, we welcome the Commission initiative to reduce unnecessary regulatory burdens while maintaining high standards for food and feed safety. We hereby submit, on behalf of EFFOP, a number of concrete measures for consideration within the Simplification Omnibus on food and feed safety.

1. Bovine Spongiform encephalopathy

As highlighted by the Commission in the Call for Evidence, the current rules under Regulation (EC) No 999/2001 (the TSE Regulation) concerning Bovine Spongiform Encephalopathy (BSE) are outdated and do not reflect recent scientific developments or the current best practices widely implemented across the feed sector.

Proportionate measures grounded in sound science are essential to ensure that BSE does not re-emerge and that new transmissible spongiform encephalopathy (TSE) agents do not arise in farmed animal populations. Since the EU-wide suspension of the use of processed animal protein (PAP) in feed for all food-producing animals in 2001, some measures have been reviewed; however, current scientific knowledge and industry practice support further, evidence-based revision.

For instance, fishmeal is a highly valuable and digestible protein source with a well-balanced amino-acid profile. Nevertheless, its use in ruminant feed is prohibited under the TSE Regulation despite EFSA's assessment that the associated health risks are minimal or non-existent[1].

The TSE Roadmap 2 has identified the potential to revise feed bans in line with scientific evidence. Modern Hazard Analysis and Critical Control Point (HACCP) systems in fishmeal production deliver high safety standards and further support regulatory updates.

We therefore encourage the Commission to examine whether the current restriction on fishmeal in ruminant feed remains justified in light of recent scientific evidence. If such a reassessment indicates that the ban is no longer warranted, lifting the prohibition on the use of fishmeal and compound feeds containing fishmeal in ruminant feed on the basis of an updated EFSA opinion would represent an important step towards better

[1] Opinion of the Scientific Panel on Biological Hazards on a request from the European Parliament on the assessment of the health risks of feeding of ruminants with fishmeal in relation to the risk of TSE, *The EFSA Journal* (2007), 443, 1-26 (https://doi.org/10.2903/j.efsa.2007.443)

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alignment of regulations with circular-economy principles. This would allow for the optimised use of approximately 10,000–20,000 tonnes per year of sustainable blue proteins while maintaining high safety standards.

2. Animal By-products and derived products

Moreover, we suggest that the legislative framework governing animal by-products and derived products not intended for human consumption (the ABP Regulations) be considered within the scope of this Simplification Omnibus.

In particular, we would like to draw attention to two specific areas:

- Requirements for transport;
- The definition of fishmeal and fish oil.

2.1. Facilitating transport of marine ingredients

Fishmeal and fish oil derive from Category 3 animal by-products and therefore their transport conditions fall under the scope of the ABP Regulations.

While we fully support the need to prevent risks to public and animal health, the implementation of the transport requirements set out in Annex VIII of Commission Regulation (EU) No 142/2011 is unharmonised across the European Union. In addition to specific cleaning processes required for the transport of fishmeal to prevent cross-contamination in relation to the TSE Regulation – which would become unnecessary if the ban on fishmeal in ruminant feed were lifted as suggested above – some Member States impose further constraints, requiring that certain products authorised for animal feed (such as fishmeal and fish oil) be carried only in vehicles or containers reserved for that purpose.

While we support strict hygiene rules to ensure safety during collection, transport and unloading, our industry faces a lack of transport availability in many regions, and the current transport rules for animal by-products create significant operational barriers.

We therefore encourage the Commission to open discussions with Member States and relevant stakeholders on the conditions for transporting animal by-products and derived products not intended for human consumption.

Regulatory changes have previously been adopted to ease the transport of liquid oils and fats intended for human consumption by sea. For example, Regulation (EU) No 579/2014 introduced an exemption to point 4 of Chapter IV in Annex II of Regulation (EC) No 852/2004 on the grounds that the requirement was impractical and imposed an unduly onerous burden on food business operators when applied to the transport by seagoing vessels of liquid oils and fats intended for, or likely to be used for, human consumption. The Commission justified that exemption by reference to the insufficient availability of seagoing vessels reserved for the transport of foodstuffs[2].

We would support an analogous examination of potential exemptions or more proportionate transport requirements for fishmeal and fish oil, which are stable, low-risk products when handled according to established hygiene standards.

2.2. Expand the definition of fishmeal and fish oil

The current definitions of fishmeal and fish oil in Annex I of Commission Regulation (EU) No 142/2011 permit the use of farmed aquatic invertebrates in their production but exclude harvested low-trophic aquatic invertebrates (such as tunicates, echinoderms and annelids).

Products derived from tunicates and echinoderms are already placed on the market for human consumption under Regulation (EC) No 853/2004. When such products are withdrawn from the food market, the resulting by-products are classified as Category 3 material under Article 10 of Regulation (EC) No 1069/2009 and may therefore be used in animal feed when processed in accordance with Regulation (EU) No 142/2011.

Taking into account the biology of marine tunicates, annelids and echinoderms, and the fact that tunicates and echinoderms are fit for human consumption, the risk profile in terms of feed safety is comparable to that of zooplankton, other marine crustaceans and molluscs (including gastropods). This assessment also considers the negligible risk of prion transmission from these species. Although the filter-feeding behaviour of marine tunicates may raise concerns regarding the bioaccumulation of undesirable substances, the regulatory framework and the industrial processes developed by fishmeal manufacturers ensure that only raw materials from which high-quality fishmeal complying with feed-safety regulations can be produced are used.

Consequently, we invite the Commission to consider the following amendments to the definitions of fishmeal and fish oil in Regulation (EU) No 142/2011 in order to ensure the legal possibility of using important sustainable marine biomass resources for feed purposes and to secure consistency between the relevant food and feed legislation:

- "fishmeal" means processed animal protein derived from aquatic animals covered by Article 4(3) of Regulation (EU) 2016/429, aquaculture animals covered by Article 4(7) of Regulation (EU) 2016/429 and other aquatic invertebrates according to Regulation (EU) 2016/429, article 4(4).

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[2] Recital 1 of the Commission Regulation (EU) No 579/2014:
"Regulation (EC) No 852/2004 provides that food business operators are to comply with the general hygiene requirements for the transport of foodstuffs set out in Chapter IV of Annex II to that Regulation. Point 4 of that Chapter requires that bulk foodstuffs in liquid, granulate or powdered form be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. However, that requirement is not practical and imposes an unduly onerous burden on food business operators when applied to the transport in seagoing vessels of liquid oils and fats intended for, or likely to be used for, human consumption. In addition, the availability of seagoing vessels reserved for the transport of foodstuffs is insufficient to serve the continuing trade in such oils and fats."

- "fish oil" means oil derived from the processing of aquatic animals covered by Article 4(3) of Regulation (EU) 2016/429, aquaculture animals covered by Article 4(7) of Regulation (EU) 2016/429 and other aquatic invertebrates according to Regulation (EU) 2016/429, article 4(4).

These amendments could potentially make an additional 100,000–200,000 tonnes per year of raw material available to European marine ingredient producers.

3. Hygiene rules

Finally, we strongly recommend that the Commission modernize selected provisions throughout the food safety legislation. In particular, improving the regulatory framework for the production of fish oil intended for human consumption will contribute to the Commission's objectives of removing unnecessary complexity, enabling innovation and strengthening the functioning of the internal market.

Fish oil is a major natural source of long-chain omega-3 polyunsaturated fatty acids, such as eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), which perform a wide range of important functions for human health. EFFOP members process Category 3 animal by-products and are therefore currently authorised to produce fish oil for feed only.

As a responsible industry, we recognise the importance of complying with strict hygiene measures and ensuring that facilities meet the standards necessary to produce fish oil for human consumption. Nevertheless, it is regrettable that a substantial proportion of raw materials that meet relevant quality criteria cannot be valorised in food markets. Industrial processes have improved significantly over the years, and appropriate hygiene rules can ensure the safety and freshness of both raw materials and final products. The European industry is committed to improving the sustainability of food and feed systems and to supplying the food market with fish oil produced from raw materials fit for human consumption, while continuing to valorise Category 3 fish by-products for the feed market.

However, European plants face a significant challenge in pursuing the production of food-grade fish oil because animal by-product materials of aquatic origin are often processed within the same establishment. It should be emphasised that seafood products have not been associated with prion-related hazards and that the risk of prion transmission through seafood consumption, including through fish oil, is non-existent.

Moreover, the hygiene rules governing the production of fish oil intended for human consumption, as set out in Chapter IV of Section VIII of Annex III to Regulation (EC) No 853/2004 and in Chapter II of Annex VI of Commission Implementing Regulation (EU) 2019/627, are not well adapted to the realities of our industry and should be updated to reflect the latest best practices implemented in European production facilities.

A concrete example concerns the use of total volatile basic nitrogen (TVB-N) as a measure to be determined when the organoleptic examination raises doubts about the freshness of the raw materials. The limit laid down – 60 mg of nitrogen per 100 g of whole fishery products (35 mg of nitrogen/100 g of flesh for *Salmo salar* and species belonging to *Merlucciidae* and *Gadidae*) used directly for the production of fish oil for human consumption – was developed for ice-stored gutted fish and fish fillets and not for whole fish used in the production of food-grade fish oil. TVB-N is a spoilage parameter indicating protein degradation, and its applicability to whole fish destined for oil extraction is limited. EFSA has likewise indicated that sensory assessment provides the most reliable indication of raw-material freshness in this context.[3]

Other requirements, such as the prescribed storage temperature of raw materials prior to processing, are likewise often unsuitable for fish oil production.

We therefore urge the Commission to revise the requirements regarding the production of fish oil intended for human consumption.

The revision should be carried out in consultation with national health authorities to ensure harmonised rules across the EU and within European economic partners, consistent requirements for the importation of fish oil from third-country, and in dialogue with stakeholders. EFFOP stands ready to provide concrete proposals and technical input to the Commission's services to help improve the regulatory framework so that European producers can supply high-quality omega-3s produced under the highest hygiene standards to European consumers.

Conclusion

EFFOP strongly supports the Commission's objective of simplifying and modernising the regulatory framework while upholding high levels of safety. The proposals set out in this response are intended to remove disproportionate burdens and to streamline compliance without reducing protection. At the same time, they contribute directly to the EU's sustainability and circularity objectives by enabling greater resource efficiency and the valorisation of marine by-products. By facilitating the use of sustainable marine biomass for feed and enabling the production of food-grade omega-3s under harmonised hygiene standards, these measures will support resilient, sustainable and competitive European food and feed systems.

[3] EFSA Panel on Biological Hazards (BIOHAZ); Scientific Opinion on Fish Oil for Human Consumption. Food Hygiene, including Rancidity. EFSA Journal 2010;8(10):1874 – Parameters for raw materials (page 35)

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